




Under the Paperwork Reduction Act of 1995, no person are required to respond to a collection of information unless it contains a valid OMB control number.

Substitute for form 1449A/PTO				Complete If Known	
 <p><b>INFORMATION DISCLOSURE STATEMENT BY APPLICANT</b></p> <p>(use as many sheets as necessary)</p>				Application Number	10/561,829
				I.A. Filing Date	June 25, 2004
				First Named Inventor	Shaharyar Khan
				Group Art Unit	1636
				Examiner Name	Kimberly A. Makar
				Attorney Docket Number	GNC 0001
Sheet	1	of	5		

[illegible][illegible]

Examiner's Signature	Date Considered	
-------------------------	--------------------	--

\*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to application.

<sup>1</sup> Unique citation designation number. <sup>2</sup> See attached kinds of U.S. Patent Documents. <sup>3</sup> Enter Office that issued the document, by the two letter code (WIPO Standard ST.3). <sup>4</sup> For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document.

\* Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST. 16 if possible. <sup>6</sup> Applicant to place a check mark here if English language Translation is attached.

**Burden Hour Statement:** This form is estimated to take 2.0 hours to complete. Time will vary depending upon the needs of the individual case. Any comments on the amount of time you are required to complete this form should be sent to the Chief Information Officer, Patent and Trademark Office, Washington, DC 20231. **DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SENT TO:** Assistant Commissioner for Patent, Washington, DC 20231.



Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid GDS control number.

Substitute for form 1449A/PTO		Complete If Known	
<b>INFORMATION DISCLOSURE STATEMENT BY APPLICANT</b>  (use as many sheets as necessary)		Application Number	10/561,829
		I.A. Filing Date	June 25, 2004
		First Named Inventor	Shaharyar Khan
		Group Art Unit	1836
		Examiner Name	Kimberly A. Makar
Sheet	2	of	5
		Attorney Docket Number	GNC 0001

OTHER ART -- NON PATENT LITERATURE DOCUMENTS			
Examiner's Initials*	Cite No.†	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published	T <sup>2</sup>
		ANZIAND and BUTOW, "Splicing-defective mutants of the yeast mitochondrial COXI gene can be corrected by transformation with a hybrid maturase gene", <i>Proc. Natl. Acad. Sci. U.S.A.</i> , 88(13):5592-6 (1991).	
		BHAT and EPELBOYM, "Quantitative analysis of total mitochondrial DNA: competitive polymerase chain reaction versus real-time polymerase chain reaction", <i>J. Biochem. Mol. Toxicol.</i> , 18(4):180-6 (2004).	
		CARROZZO, et al., "Maternally-inherited Leigh syndrome-related mutations bolster mitochondrial-mediated apoptosis", <i>J. Neurochem.</i> , 90(2):490-501 (2004).	
		CERVIN, et al., "Cosegregation of MIDD and MODY in a pedigree: functional and clinical consequences", <i>Diabetes</i> , 53(7):1894-9 (2004).	
		CHEN, et al., "Determination of normal ranges of mitochondrial respiratory activities by mtDNA transfer from 54 Human subjects to mtDNA-less HeLa cells for identification of the pathogenicities of mutated mtDNAs", <i>J. Biochem. (Tokyo)</i> , 135(2):237-43 (2004).	
		CLAROS and VINCENS, "Computational method to predict mitochondrially imported proteins and their targeting sequences", <i>Eur. J. Biochem.</i> , 241(3):779-86 (1996).	
		D'SOUZA, et al., "DQAsome-mediated delivery of plasmid DNA toward mitochondria in living cells", <i>J. Control. Release</i> , 92(1-2):189-97 (2003).	
		FALKENBERG, et al., "Mitochondrial transcription factors B1 and B2 activate transcription of human mtDNA", <i>Nat. Genet.</i> , 31(3):289-94 (2002).	
		FORTUNATI, et al., "A multi-domain protein for beta1 integrin-targeted DNA delivery", <i>Gene Ther.</i> , 7(17):1505-15 (2000).	
		FUTAKI, et al., "Arginine-rich peptides. An abundant source of membrane-permeable peptides having potential as carriers for intracellular protein delivery", <i>J. Biol. Chem.</i> , 276(8):5836-40 (2001).	
		GROSSCHEDL, et al., "HMG domain proteins: architectural elements in the assembly of nucleoprotein structures", <i>Trends Genet.</i> , 10(3):94-100 (1994).	

Examiner's Signature	Date Considered
----------------------	-----------------

\*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to application.

† Unique citation designation number ‡ See attached Kinds of U.S. Patent Documents. § Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). ¶ For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document.

\* Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST. 16 if possible. ¶ Applicant to place a check mark here if English language Translation is attached.

Burden Hour Statement: This form is estimated to take 2.0 hours to complete. Time will vary depending upon the needs of the individual case. Any comments on the amount of time you are required to complete this form should be sent to the Chief Information Officer, Patent and Trademark Office, Washington, DC 20231. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SENT TO: Assistant Commissioner for Patent, Washington, DC 20231.



Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number.

Substitute for form 1449A/PTO  <b>INFORMATION DISCLOSURE STATEMENT BY APPLICANT</b>  (use as many sheets as necessary)		<b>Complete if Known</b>			
		Application Number	10/561,829		
		I.A. Filing Date	June 25, 2004		
		First Named Inventor	Shaharyar Khan		
		Group Art Unit	1636		
		Examiner Name	Kimberly A. Makar		
Sheet	3	of	5	Attorney Docket Number	GNC 0001

OTHER ART -- NON PATENT LITERATURE DOCUMENTS			
Examiner's Initials*	Cite No. <sup>1</sup>	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published	T <sup>2</sup>
		GUY, et al., "Rescue of a mitochondrial deficiency causing Leber Hereditary Optic Neuropathy", <i>Ann. Neurol.</i> , 52(5):534-42 (2002).	
		IGNATOVICH, et al., "Complexes of plasmid DNA with basic domain 47-57 of the HIV-1 Tat protein are transferred to mammalian cells by endocytosis-mediated pathways", <i>J. Biol. Chem.</i> , 278(43):42625-36 (2003).	
		KHADAKE and RAO, "Condensation of DNA and chromatin by an SPKK-containing octapeptide repeat motif present in the C-terminus of histone H1", <i>Biochemistry</i> , 36(5):1041-51 (1997).	
		KRUEGER, et al., "Peripheral-type benzodiazepine receptors mediate translocation of cholesterol from outer to inner mitochondrial membranes in adrenocortical cells", <i>J. Biol. Chem.</i> , 265(25):15015-22 (1990).	
		LEVY, et al., "Cytoplasmic transfer in oocytes: biochemical aspects", <i>Hum. Reprod. Update</i> , 10(3):241-50 (2004).	
		LIU, et al., "Mitochondrial DNA mutation and depletion increase the susceptibility of human cells to apoptosis", <i>Ann. N.Y. Acad. Sci.</i> , 1011:133-45 (2004).	
		LU and HANSEN, "Revisiting the structure and functions of the linker histone C-terminal tail domain", <i>Biochem. Cell Biol.</i> , 81(3):173-6 (2003).	
		LUO and SALTZMAN, "Synthetic DNA delivery systems", <i>Nat. Biotechnol.</i> , 18(1):33-7 (2000).	
		NEUPERT, "Protein import into mitochondria", <i>Annu. Rev. Biochem.</i> , 66:863-917 (1997).	
		NOGUCHI and MATSUMOTO, "Protein transduction technology offers a novel therapeutic approach for diabetes", <i>J. Hepatobiliary Pancreat. Surg.</i> , 13(4):306-13 (2006).	
		OCA-COSSIO, et al., "Limitations of allotropic expression of mitochondrial genes in mammalian cells", <i>Genetics</i> , 165(2):707-20 (2003).	

Examiner's Signature	Date Considered
----------------------	-----------------

\*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to application.

<sup>1</sup> Unique citation designation number <sup>2</sup> See attached Kinds of U.S. Patent Documents. <sup>3</sup> Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). <sup>4</sup> For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. <sup>5</sup> Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST. 16 if possible. <sup>6</sup> Applicant to place a check mark here if English language Translation is attached.

Burden Hour Statement: This form is estimated to take 2.0 hours to complete. Time will vary depending upon the needs of the individual case. Any comments on the amount of time you are required to complete this form should be sent to the Chief Information Officer, Patent and Trademark Office, Washington, DC 20231. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SENT TO: Assistant Commission for Patent, Washington, DC 20231.



Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number.

Substitute for form 1449A/PTO		Complete if Known	
<b>INFORMATION DISCLOSURE STATEMENT BY APPLICANT</b>  (use as many sheets as necessary)		Application Number	10/561,829
		I.A. Filing Date	June 25, 2004
		First Named Inventor	Shaharyar Khan
		Group Art Unit	1636
		Examiner Name	Kimberly A. Makar
		Attorney Docket Number	GNC 0001
Sheet	4	of	5

OTHER ART -- NON PATENT LITERATURE DOCUMENTS			
Examiner's Initials*	Cite No. <sup>1</sup>	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published	T <sup>2</sup>
		PETROS, et al., "mtDNA mutations increase tumorigenicity in prostate cancer", <i>Proc. Natl. Acad. Sci. U.S.A.</i> , 102(3):719-24 (2005).	
		PINEAU, et al., "Targeting the NAD7 subunit to mitochondria restores a functional complex I and a wild type phenotype in the <i>Nicotiana sylvestris</i> CMS II mutant lacking nad7", <i>J. Biol. Chem.</i> , 280(28):25994-6001 (2005).	
		PROSITE Documentation PDOC00305, "HMG boxes A and B and DNA-binding domains signature and profile", updated December 2004.	
		RANTANEN and LARSSON, "Regulation of mitochondrial DNA copy number during spermatogenesis", <i>Hum. Reprod.</i> , 15 Suppl 2:86-91 (2000).	
		ROSS and MURPHY, "Cell-penetrating peptides are excluded from the mitochondrial matrix", <i>Biochem. Soc. Trans.</i> , 32(Pt 6):1072-4 (2004).	
		ROSSIGNOL, et al., "Mitochondrial threshold effects", <i>Biochem. J.</i> , 370(Pt 3):751-62 (2003).	
		ROUBERTOUX, et al., "Mitochondrial DNA modifies cognition in interaction with the nuclear genome and age in mice", <i>Nat. Genet.</i> , 35(1):65-9 (2003).	
		ROUCOU, et al., "Bioenergetic and structural consequences of allotopic expression of subunit 8 of yeast mitochondrial ATP synthase. The hydrophobic character of residues 23 and 24 is essential for maximal activity and structural stability of the enzyme complex", <i>Eur. J. Biochem.</i> , 261(2):444-51 (1999).	
		SCHAEFER, et al., "The epidemiology of mitochondrial disorders--past, present and future", <i>Biochim. Biophys. Acta</i> , 1659(2-3):115-20 (2004).	
		SEIBEL, et al., "Transfection of mitochondria: strategy towards a gene therapy of mitochondrial DNA diseases", <i>Nucleic Acids Res.</i> , 23(1):10-7 (1995).	
		SMIGROZKI and KHAN, "Mitochondrial microheteroplasmy and a theory of aging and age-related disease", <i>Rejuvenation Res.</i> , 8(3):172-98 (2005).	

Examiner's Signature	Date Considered
----------------------	-----------------

\*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to application.

<sup>1</sup> Unique citation designation number. <sup>2</sup> See attached Kinds of U.S. Patent Documents. <sup>3</sup> Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). \* For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. \* Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST. 16 if possible. \* Applicant to place a check mark here if English language Translation is attached.

Burden Hour Statement: This form is estimated to take 2.0 hours to complete. Time will vary depending upon the needs of the individual case. Any comments on the amount of time you are required to complete this form should be sent to the Chief Information Officer, Patent and Trademark Office, Washington, DC 20231. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SENT TO: Assistant Commissioner for Patent, Washington, DC 20231.



Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number.

Substitute for form 1449A/PTO		Complete If Known			
<b>INFORMATION DISCLOSURE STATEMENT BY APPLICANT</b>  (use as many sheets as necessary)		Application Number	10/561,829		
		I.A. Filing Date	June 25, 2004		
		First Named Inventor	Shaharyar Khan		
		Group Art Unit	1636		
		Examiner Name	Kimberly A. Makar		
Sheet	5	of	5	Attorney Docket Number	GNC 0001

OTHER ART -- NON PATENT LITERATURE DOCUMENTS			
Examiner's Initials*	Cite No. <sup>1</sup>	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published	T <sup>2</sup>
		SRIVASTAVA and MORAES, "Manipulating mitochondrial DNA heteroplasmy by a mitochondrially targeted restriction endonuclease", <i>Hum. Mol. Genet.</i> , 10(26):3093-9 (2001).	
		STEPHENS and PEPPERKOK, "The many ways to cross the plasma membrane", <i>Proc. Natl. Acad. Sci. U.S.A.</i> , 98(8):4295-8 (2001).	
		SUBIRANA, "Analysis of the charge distribution in the C-terminal region of histone H1 as related to its interaction with DNA", <i>Biopolymers</i> , 29(10-11):1351-7 (1990).	
		SUZUKI, et al., "An NMR study on the DNA-binding SPKK motif and a model for its interaction with DNA", <i>Protein Eng.</i> , 6(6):565-74 (1993).	
		SUZUKI, et al., "Maternal inheritance of diabetes is associated with inactive ALDH2 genotype in diabetics with renal failure in Japanese", <i>Diabetes Res. Clin. Pract.</i> , 60(2):143-5 (2003).	
		TANAKA, et al., "Gene therapy for mitochondrial disease by delivering restriction endonuclease SmaI into mitochondria", <i>J. Biomed. Sci.</i> , 9(6 Pt 1):534-41 (2002).	
		TAYLOR, et al., "Mitochondrial DNA mutations in human colonic crypt stem cells", <i>J. Clin. Invest.</i> , 112(9):1351-60 (2003).	
		WANG, et al., "Acquisition of double-stranded DNA-binding ability in a hybrid protein between Escherichia coli CspA and the cold shock domain of human YB-1", <i>Mol. Microbiol.</i> , 38(3):526-34 (2000).	
		VESTWEBER and SCHATZ, "DNA-protein conjugates can enter mitochondria via the protein import pathway", <i>Nature</i> , 338(6211):170-2 (1989).	
		WEIR, et al., "Structure of the HMG box motif in the B-domain of HMG1", <i>EMBO J.</i> , 12(4):1311-8 (1993).	
		ZULLO, et al., "Stable transformation of CHO Cells and human NARP cybrids confers oligomycin resistance (oli(r)) following transfer of a mitochondrial DNA-encoded oli(r) ATPase6 gene to the nuclear genome: a model system for mtDNA gene therapy", <i>Rejuvenation Res.</i> , 8(1):18-28 (2005).	

Examiner's Signature	/Qian Janice Li/ (10/02/2009)	Date Considered	
----------------------	-------------------------------	-----------------	--

\*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to application.

<sup>1</sup> Unique citation designation number <sup>2</sup> See attached Kinds of U.S. Patent Documents. <sup>3</sup> Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). <sup>4</sup> For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document.

<sup>5</sup> Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST. 16 if possible. <sup>6</sup> Applicant to place a check mark here if English language Translation is attached.

Burden Hour Statement: This form is estimated to take 2.0 hours to complete. Time will vary depending upon the needs of the individual case. Any comments on the amount of time you are required to complete this form should be sent to the Chief Information Officer, Patent and Trademark Office, Washington, DC 20231. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SENT TO: Assistant Commissioner for Patent, Washington, DC 20231.